UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT

Dated: June 26, 2009

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PRELIMINARY STATEMENT[1]

In 1984, Congress enacted the Hatch-Waxman Act in an effort to encourage the use of generic drugs in the United States. Dey was a small entrepreneurial company who saw opportunity in generic competition, and so developed and launched generic alternatives to brand albuterol, cromolyn, and ipratropium bromide in the mid-1990s. Those generic products saved the Medicare and Medicaid programs a great deal since reimbursement levels for generic drugs were much lower than for the brand name drugs. In competing in this market, Dey followed what it believed was industry practice in setting an Average Wholesale Price, or AWP, in order to be listed as a generic product. It also published its Wholesale Acquisition Cost, or WAC, which it used as its wholesale invoice price and which it continually lowered as competition drove prices down. From 1999 on, it sent repeated letters to Medicaid agencies explicitly advising them what Dey's published AWP and WAC represented.

Against this background and this record, Dey moves for summary judgment to limit the time for which the United States (the "Government") can seek damages under the False Claims Act (31 U.S.C. 3729, *et seq.*) (the "FCA") from October 1992 to August 1997 for albuterol, May 1994 to August 1997 for cromolyn sodium, and January 1997 to January 1999 for ipratroprium bromide. As will be shown, the Centers for Medicare & Medicaid Services ("CMS"), formerly known as the Health Care Services Administration, and state Medicaid agencies had a host of information concerning Dey's actual invoice prices starting with actual invoices of Dey's albuterol products for 1994, published declining WACs, Average Manufacturer Prices, ("AMPs"), published Federal Supply Schedule ("FSS") prices, state surveys prices and other

[1] In its motion for pretrial summary judgment, Dey relies on the evidence set forth in Dey's Rule 56.1 Statement ("SOF"), the exhibits attached to the declaration of Sarah L. Reid (hereinafter referred to as "Ex.__"), as well as on the affidavit of Pamela Marrs ("Marrs Aff."), and the declarations of W. David Bradford, Ph.D. ("Bradford Decl."), and Lauren J. Stiroh, Ph.D. ("Stiroh Decl.").

information. Indeed, inhalation drugs, and specifically Dey's drugs, were a repeated focus of CMS, the Department of Health and Human Services Office of the Inspector General ("OIG"), and the Department of Justice, who was investigating the *qui tam* action filed in August 1997. By 1999 at the latest, when Dey started sending its letters in an effort to make sure that there was no misunderstanding as to what Dey's published prices were, the "perfect storm of knowledge" for Dey's drugs occurred. At that point, any continued use of these reported prices was the result of reasoned choices by competent regulators to set reimbursement for these important inhalation drugs at a level the agencies felt were necessary to maintain a provider distribution network. Many of these regulators set Maximum Allowable Costs ("MACs") for the Subject Drugs, and CMS set Federal Upper Limits ("FULs"). Even after Dey sent its letters, CMS continued to obtain information regarding Dey's drugs, including the circulation and ultimate rejection of the lower, revised AWP prices published for Dey's albuterol and cromolyn in September, 2000.

Dey also moves for summary judgment to limit the damages in this case to the states and time periods for which the Government has produced state-specific claims data and to the time periods where the Government has produced DMERC arrays containing Dey's products for Medicare median calculation. In addition, Dey moves for summary judgment dismissing all Medicaid claims paid on SMACs, usual and customary charges, FULs, amounts not authorized by the relevant methodology, and other reimbursement bases not related to Dey's published prices. Finally, Dey moves for summary judgment on the grounds that the Government cannot succeed on its unjust enrichment claim.[2]

[2] The Court has held that the statute of limitations bars any unjust enrichment claims prior to August 23, 2000. *United States ex rel. Ven- A-Care of the Fla. Keys, Inc. v. Dey, Inc.*, 498 F. Supp. 2d 389, 400-01 (D. Mass. 2007).

A. Dey and the Launch of its Generic Respiratory Products

Dey is a small, specialty pharmaceutical manufacturer focused on the development, manufacturing, and marketing of prescription drugs used to treat respiratory diseases and allergies. (Marrs ¶ 4.) Dey was founded in Texas in 1978 by four entrepreneurs. (Marrs ¶ 5.) Initially, its primary products were unit-dose sodium chloride solution inhalation solutions, and its primary customers were hospitals. (Marrs ¶¶ 6, 9.)

In the late 1980s, Dey submitted an abbreviated new drug application ("ANDA") for albuterol sulfate ("albuterol") unit dose. (Marrs ¶ 15.) That same time, Dey acquired a facility in Napa, California and relocated its manufacturing, marketing and sales functions there. (Marrs ¶¶ 10, 11.) The manufacturing capacity at the Napa facility gave Dey the capacity to manufacture albuterol sulfate in unit dose vials. (Marrs ¶ 12.)

In 1992, the FDA approved Dey's albuterol unit dose ANDA, and the product launched in March of that year. (Marrs ¶ 16.) At the time of its launch, it was not only the first generic unit dose albuterol to market, but it was also the first BAC-preservative-free albuterol unit dose product on the market. (Marrs ¶ 17.)

With the launch of albuterol unit dose, Dey began breaking into other markets, including homecare, and to a lesser extent, retail. (Marrs ¶ 19.) Dey pursued opportunities to launch other generic respiratory inhalation solutions, and launched cromolyn sodium ("cromolyn") and ipratropium bromide ("ipratropium") products in May, 1994 and January, 1997, respectively. (Marrs ¶¶ 30, 33, 36.) (Dey's albuterol, ipratropium, and cromolyn products are referred to herein as the "Subject Drugs".)

B. Dey's Pricing

Dey understood that for a pharmaceutical product to be recognized as a generic, it must be listed by the publishing compendia as a generic. (SOF ¶ 68.) Dey learned from Ed Edelstein

of First DataBank that, in order to be recognized as a generic, the published generic Average Wholesale Price ("AWP") had to have been set at least 10% less than the brand AWP prior to any sales for that drug. (*Id*.) Accordingly, in 1992 for its albuterol and thereafter for the other Subject Drugs, at launch and prior to any sales, Dey set the AWP for its generic drugs at roughly 10% below the brand AWP. (SOF ¶ 70; Marrs Aff. ¶¶ 16, 24, 33, 36.) It then left that number alone, as it believed was industry practice, and it used its published Wholesale Acquisition Cost ("WAC") as its invoice price. (SOF ¶¶ 70, 73.)

Dey invoiced its sales to wholesalers at Wholesale Acquisition Cost ("WAC"), which was the list price for the product and the price against which discounts and chargebacks were applied as applicable. (SOF ¶¶ 73-75; Stiroh Decl. ¶ 9.) Dey lowered its WAC regularly and it reported that lowered WAC regularly to the publishing compendia for each of the Subject Drugs from 1992 to date. (SOF ¶¶ 74-76.) The WAC Dey reported throughout the time period at issue is the WAC as defined by Congress in 2003 in U.S.C.A. § 1395w-3a(c)(6)(B).

In 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90") which created the Medicaid rebate program which lowered each state program's Medicaid costs through rebates from drug manufacturers pursuant to contract. (SOF ¶ 85.) In this legislation, Congress also created and defined the Average Manufacturer Price ("AMP"), the average price, net of discounts, that a manufacturer had to report to CMS for the calculation of rebates and to provide the states with a "baseline for reimbursement" (SOF ¶¶ 85, 86.) Dey signed a Rebate Agreement with the Secretary of Health and Human Services pursuant to 42 U.S.C. § 1396r-8(a)(1) in 1991, and has reported its AMPs as defined in the Rebate Agreement for its products including the ones at issue here since then. (SOF ¶¶ 88, 90.) It has also reported

its Average Sales Prices ("ASPs") as required since the enactment of the Medicaid Modernization Act in 2003. (SOF ¶¶ 106-109.)

C. Price Competition in the Generic Drug Market

The generic market is characterized by intense competition. While the brand price may remain the same or even increase in the face of generic competition, the price of each generic alternative typically falls as more generic companies enter the market. (SOF ¶¶ 58, 59.) Dey's pricing behavior reflects that competitive environment. (SOF ¶ 40; Stiroh Decl., Figures A-K.) The prices of Dey's products fall over time as Dey is forced to match or beat its competitors' prices to maintain or win sales. (*Id.*)

In 1984, recognizing the potential benefit from stiff price competition in the market for generics, Congress enacted the Hatch-Waxman Act in an effort to encourage the use of generic drugs in the United States and to lower the cost of prescription drugs for American consumers through generic competition. (SOF ¶ 55.) After the passage of the Hatch-Waxman Act, states and federal agencies began to mandate the use of generics in the place of brands when available. (SOF ¶ 56, 60.) These initiatives have paid off, lowering Medicaid and Medicare expenditures. For example, in 1992, when no generic competition existed for Proventil (albuterol) 0.083% solution, Medicaid paid about $59.81 per prescription. (Bradford Decl. ¶ 14.) By 2000, when generic competition for this drug was well established, average Medicaid spending per prescription fell to $31.55. (*Id.*) In fact, the amount that Medicaid typically paid for the brand had continued to rise to $106.67 per prescription in 2000, while it typically paid $26.99 for Dey's generic. (*Id.*)

While the prices of generics fall from the increased competition, the pharmacy must earn at least as large of a dollar margin on the generic as on the brand in order for it to make economic sense to dispense the generic. (Bradford Decl. ¶ 13.) As an example, the dollar

margin for the pharmacist to dispense Dey's generic albuterol must be the same as the margin on Proventil. This means that the percentage margin on generics will be higher, even though the overall cost to Medicaid is much lower. (Bradford Decl. ¶¶ 9-10; Stiroh Decl., Figures A-K 13, 14.) Looking solely at these "percentage spreads" in the generic context is therefore misleading.

The stiff price competition in the generic market has forced Dey to repeatedly lower the prices for its drugs. This is clearly reflected in Dey's published WACs, the prices Dey invoices wholesalers, which have declined throughout the relevant time period as new market entrants have increased competition. (SOF ¶¶ 73-80; Stiroh Decl., Figures A-K.) Indeed today, Dey only sells two of the six challenged inhalation products, albuterol unit dose and ipratropium bromide. (Stiroh Decl., Table 1.) For these remaining products, Dey loses money on albuterol unit dose and barely breaks even on ipratropium bromide. (Marrs Aff. ¶¶ 22, 39.) Ironically when Dey's WAC prices were highest in the initial years of entrance, the "spread" between AWP and WAC was the lowest. (Stiroh Decl., Figures A-K.) For example, when Dey launched its cromolyn 49502-0689-12 in 1994 as the first generic to market, its AWP was $84.00 per package and its WAC was $67.20, resulting in a spread of 20%. (Stiroh Decl., Figure K.) It is only as price competition drove the WAC prices down that challenged mega-spreads occurred. (*Id.*)

D. Government Investigations and the *Qui Tam* Lawsuit

In October of 1997, Dey received a subpoena from the Government concerning its reporting of AWP to the compendia. (Marrs Aff. ¶ 49.) Almost all of the marketing material relied on by the Government in the Dey case predates that subpoena. In January of 1999, after Dey had met with the Department of Justice ("DOJ"), Dey began sending letters to Medicaid agencies and in some instances the DMERCs explicitly detailing what its reported AWP and WACs were. (SOF ¶¶ 148-158.) These letters were sent when there was a product price change

so that there could be no possibility of confusion, let alone fraud. A typical letter included the following language:

> …As you know, WAC is referred to by data reporting services and government agencies as an "estimate," and Dey believes that WAC generally means the invoice price charged by a pharmaceutical manufacturer to drug wholesalers. As you also know, WAC does not include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees, and other such cost adjustments which are well-known and commonplace in the pharmaceutical industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be determined until some months after the date of invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which you are reimbursing under Medicaid.

Ex. 111. (emphasis in the original). The letters describe Dey's AWP as follows:

> Further, as you also know, the Average Wholesale Price (or "AWP") per unit listed above does not represent actual wholesale prices which will be charged or paid for this product. It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators. *Id*.

Also in August, 1997, a sealed qui tam action was filed against Dey by Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care" or "Relator"). (SOF ¶ 142.) The Government waited nine years to unseal that action which seeks damages, for the federal share of Medicaid to the date of trial and for Medicare through 2004.[3] (SOF ¶ 149.) At the time of unsealing, Dey no longer sold 4 of the 6 subject drug products, 17 of the challenged NDCs were obsolete. (Stiroh Decl., Table 1.)

E. State Medicaid Reimbursement Choice

The Medicaid program is a joint federal and state program under which the Government provides funds to the States for medical assistance programs for indigent individuals. *See generally* 42 U.S.C. § 1396. In 1987, the Centers for Medicare and Medicaid Services ("CMS"),

[3] This Court has already held that Medicare claims are barred after 2003. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 31-32 (D. Mass. 2007).

then known as the Health Care Financing Administration, after a Task Force report and recommendation, enacted regulations 42 C.F.R §§ 447.301 to 447.333 which gave the states the ability to experiment with methods of lowering prescription drug reimbursement to providers for their Medicaid programs so long as each state met its aggregate limits and a provider network sufficient to guarantee access to every Medicaid recipient in every state. (SOF ¶¶ 207-212, 214-217, 220, 221.) Because of this flexibility, each state Medicaid program is able to weigh various unique local considerations and, as a result, often make different choices when deciding on prescription drug reimbursement rates. (SOF ¶¶ 214, 216, 265-281.) As the OIG stated in its 2001 report regarding HIV and AIDS drugs, there are three components to rate setting for prescription drugs: ingredient cost, dispensing fee and rebates. (Ex. 38 at 3-4, 7.) Ultimately, the reimbursement rates selected by each state Medicaid program are the result of choosing among these components driven by negotiations with or legal action from pharmacy groups deliberately, complying with legislative mandates, and ensuring Medicaid recipients have access to services by providing sufficient margin between a provider's acquisition cost and whatever formula a state chooses so that providers remain in the program. (SOF ¶ 271.)

A review of state Medicaid programs during the relevant time period clearly shows that, because each state had to address local considerations and realities, there is wide variation in reimbursement rates. However, the ingredient cost and dispensing fees for all of these variations have been approved by CMS as part of the state plan process. (SOF ¶¶ 211, 214, 215.) State Medicaid programs have generally reimbursed for the ingredient cost of each drug based on the lowest of the EAC as set by the states, the MAC set by the state, the FUL, the providers' usual and customary charge, or other state-specific bases. (SOF ¶ 273.) AWP and WAC are but one element in state Medicaid reimbursement.

First, states are faced with a choice regarding which pricing benchmark to use in their EAC calculation, although almost all require generic substitution because it is generally cheaper than the brand. Most states have chosen an AWP minus formula, but some have relied on WAC pricing data. (SOF ¶ 276.) Still others have used one benchmark only to switch to another benchmark at a different point in time. *See*, Florida (WAC pricing to AWP-based reimbursement and back to WAC). (SOF ¶ 277.) Furthermore, some states have frequently revised the discount on AWP or WAC and others have chosen not to revise the calculation or modify it only rarely. *See,* e.g., Alaska, which has maintained its EAC at AWP-5% since 1990, and Minnesota which has modified its EAC formula four different times in the span of about ten years, from AWP-10%, AWP-14%, AWP-11.5% and then to AWP-12%. (SOF ¶ 278.)

More importantly, states routinely impose MACs or rely on FULs for particular drugs as a way to control costs, and Dey's Subject Drugs were often subject to such caps. (Bradford Decl. ¶¶ 23, 25.) These MACs are frequently not based on compendia prices. (SOF ¶¶ 235-237.) Some states MAC prices are based on a proprietary formula by a subcontractor (*See, e.g.*, Georgia, New Hampshire and North Carolina), others on surveying providers about their invoice or actual acquisition costs (Arkansas, Minnesota, Tennessee and Texas). (SOF ¶¶ 280, 281.) Forty-five percent of the claims for the subject drugs were paid on the basis of SMAC and FUL for the Subject Drugs. (Bradford Decl. ¶ 25.) It must be noted that these percentages include only those claims for which claims data was produced. As a result of the Government's delay in bringing this action and failure to make sure such information was preserved, much of the SMAC data has been lost. The inability to retrieve that data now prejudices Dey.[4]

[4] *See* Dey's Motion for a Finding of Spoliation and for Sanctions (Docket 6109), Memorandum of Law in Support of its Motion for a Finding of Spoliation and for Sanctions (Docket 6110), and supporting Declaration of Sarah L. Reid (Docket 6111), which is incorporated herein.

The notion that state Medicaid regulators were somehow unaware or uninformed as to Dey's prices is misplaced. States did surveys, set MACs, and received Dey's letters telling them what its WAC and AWP were. (SOF ¶ 282.) They regularly met with each other and with CMS and shared information. (SOF ¶ 283.) Each state has its own story as to the choices it made and CMS signed off on those choices through state plan amendments.

Furthermore, CMS instituted FULs for Dey's albuterol and ipratropium NDCs at issue at different points during the time period at issue. (SOF ¶ 242.) CMS officials were taught by other CMS officials how to exercise their discretion to set FULs manually so as to meet the dual objectives of cost savings and access. (SOF ¶ 244.) Despite regulations stating otherwise, CMS based FULs on prices that were not the lowest published prices. (*Id.*)

F. Medicare Reimbursement

The Medicare program is administered by CMS, which contracts with private insurance carriers to administer and pay Part B claims from the Medicare Trust Fund. (SOF ¶ 162.) In 1993, increased utilization of drugs used with durable medical equipment ("DME") and the existence of unique provider groups led CMS to create a system with separate fiscal intermediaries to process DME related claims. (SOF ¶ 163.) CMS created four regions, each with a separate fiscal intermediary. The regional fiscal intermediaries are referred to as Durable Medical Equipment Regional Carriers ("DMERCs"). (*Id.*) Dey's Subject Drugs are all administered via a nebulizer which is classified as durable medical equipment and are therefore reimbursed through the DMERCs. (SOF ¶ 164.) DMERCs are agents of CMS, and CMS communicated its directives to the DMERCs through published Program Memoranda. (SOF ¶ 165.)

Medicare reimburses for covered prescription drugs by using a 5-digit alphanumeric code, the Healthcare Common Procedural Coding System ("HCPCS" or "HCPCS Code"), which

are not unique to product size, packaging or dose. (SOF ¶ 167, 168.) To determine the ingredient payment level for multi-source drugs, the DMERCs collected an AWP for all NDCs relevant to each HCPCS from pricing compendia known as Redbook. (SOF ¶ 170.) This list of NDCs and prices was commonly known as the pricing array. (*Id.*) Each DMERC compiled a pricing array for each HCPCS on a quarterly basis and calculated the median generic or lowest brand price to determine the allowed reimbursement level. (*Id.*) Although payment policies for Medicare Part B are set at the Federal level, regional DMERCs had considerable latitude in implementing these policies. (SOF ¶ 171.)

From 1992 to 1997, the Medicare ingredient reimbursement formula was the lower of (1) the billed charge from the provider, or (2) the lower of the Estimated Acquisition Cost ("EAC") or the median AWP of all of the generic forms of the products in the relevant code. (SOF ¶ 175.) In 1997, Congress refused to implement the Clinton proposal moving to an actual acquisition cost plus basis of reimbursement and instead changed the reimbursement formula to 95 percent of the median AWP for drugs within a single HCPCS code. (SOF ¶ 182.) This information was transmitted to carriers and DMERCs in a Program Memoranda dated January, 1998. (SOF ¶ 180.) From 1999 to 2003, Medicare reimbursed Part B covered drugs at 95 percent of the lower of the median published AWP for the generic drugs in the code or the AWP of the least expensive brand-name drug. (SOF ¶ 185.) CMS continuously restated this formula for calculating the median AWP through program memoranda issued in September 1999, November, 2000 and May, 2002. (SOF ¶ 187.) In its instructions to carriers, CMS consistently defined AWP as "the AWP as reflected in sources such as the Red Book, Blue Book or Medispan." (SOF ¶ 183.) Throughout the period at issue, Medicare would only use the AWP basis if it were lower than the provider billed charge. (SOF ¶ 174.)

Moreover, CMS has the authority to adjust grossly excessive Medicare reimbursement payments to insure that they are "inherently reasonable." *See* 42 U.S.C. § 1395u(b)(8). In 1998, in response to the inherent reasonableness clause, the DMERCs surveyed the prices paid by providers for several products, including albuterol sulfate, reimbursed under Medicare Part B. (SOF ¶ 192.) As a result of the survey the internal medical director for region D recommended that an "… Inherent Reasonableness reduction of 15% in 1998 for albuterol sulfate 0.083% is clearly warranted and supportable". (SOF ¶ 193.) In 1999, Congress passed legislation prohibiting CMS from using the inherent reasonableness clause until the GAO conducted a study to examine the CMS's effort. (SOF ¶ 194.) One question posed by Congress for the GAO study was the issue of access due to the proposed reduced reimbursement levels. (*Id*.)

ARGUMENT

I. LEGAL STANDARDS

A. Legal Standard for Summary Judgment

Summary judgment should be granted where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 139 (D. Mass. 2008). "To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party's position." *Id*. (citing *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir. 1990)).

B. Legal Standard Under the FCA

This is primarily an FCA action brought under sections 3729(a)(1) and (2).[5] The FCA requires that a party knowingly submit a false claim. Dey vigorously disputes that it ever

[5] Plaintiffs have stipulated to the dismissal of their common law fraud claim with prejudice. *See* Docket 6163.

intended to deceive anyone as to its prices or to cause any "false claim" to be submitted by any provider but recognizes based on this Court's prior rulings[6] that that is an issue of fact for the time period until 1997 for albuterol and cromolyn and 1999 for all of Dey's products. After that date however, consistent with this Court's prior rulings, there can be no doubt that CMS understood what Dey's published prices were. Similarly, there can be no FCA damages without causation which the Government as a matter of law cannot show for the categories of damages set forth hereafter.

To establish liability under section 3729(a)(1), the Government must prove that Dey "knowingly present[ed], or caus[ed] to be presented, to an officer or employee of the United States Government … a false or fraudulent claim for payment or approval." *See* 31 U.S.C.§ 3729(a)(1). To establish liability under section 3729(a)(2), the Government must prove that Dey "knowingly [made], us[ed], or caus[ed] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." To establish liability under sections 3729(a)(1) and (a)(2), the Government must prove the existence of an actual claim for payment. *See United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 437-44 (3d Cir. 2003).

The falsity element of claims under 3729(a)(1) and (a)(2) can be negated when the Government "possess[es] knowledge of the actual true facts of the claim." *Mylan Labs.*, 608 F. Supp. at 148; *see also United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 544-45 (7th Cir. 1999).

The Government must also prove that Dey had the requisite scienter for FCA liability. Section 3729(b) defines "knowing" and "knowingly" as: (1) having actual knowledge of the falsity; (2) acting in deliberate ignorance of the truth or falsity; or (3) acting in reckless disregard

[6] While one of the Court's rulings is presently *sub judice* before the First Circuit, others are not yet appealable.

of the truth or falsity. *See* 31 U.S.C.§ 3729(b)(1)(i)-(iii). The Government's knowledge can also negate the scienter element "when the government's knowledge [of the defendant's] actions is so *extensive* that the defendant could not as a matter of law possess the requisite state of mind to be liable under the FCA." *Mylan Labs.*, 608 F. Supp. 2d at 149; *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 951-53 (10th Cir. 2008).

The FCA specifically places the burden of proving claimed damages on the Government. 31 U.S.C. § 3731(c). *See United States v. Advance Tool Co.*, 902 F. Supp. 1011, 1017 (W.D. Mo. 1995), *judgment aff'd*, 86 F.3d 1159 (8th Cir. 1996) (court limited to awarding civil penalties where plaintiff failed to demonstrate actual damages). Moreover, to recover damages under the FCA, the Government must prove that it suffered actual damages *as a result of* the defendant's allegedly false statement. *See* 31 U.S.C. § 3729(a). Courts have refused to award the Government any damages under the FCA where the government had failed to demonstrate that the defendant's false statements were the "direct and proximate cause of [the Government's] losses." *United States ex rel. Fago v. M & T Mortgage Corp.*, 518 F. Supp. 2d 108, 122 (D.D.C. 2007) (court granted the defendant summary judgment as to the plaintiff's claim for FCA damages because the plaintiff had failed to prove causation); *United States v. Hibbs*, 568 F.2d 347, 349 (3d Cir. 1977) (holding that, in assessing damages under the FCA, "a causal connection must be shown between loss and fraudulent conduct"). The Government must prove its claims by a preponderance of the evidence. *See* Section 3731(c) ("the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.").

II. PARTIAL SUMMARY JUDGMENT SHOULD BE GRANTED LIMITING THE TIME FRAME FOR ANY RECOVERY

Although Dey contends – and will show at trial – that the Government cannot recover on any of its claims, there are two points in time after which, for independent reasons, the Government cannot recover damages as a matter of law. First, by 1997 for Dey's albuterol sulfate and cromolyn sodium, and by 1999 for all of Dey's drugs, the Government's knowledge of Dey's prices – gained through its own investigation as well as through disclosure made by Dey – was so extensive that there could simply be no "false" claim after that point. Second, the Government was in a position to begin litigating this action in 1997, but instead kept it under seal for nine years, allowing its alleged damages to increase in value while gaining a tactical advantage over Dey. Allowing the Government to seek damages that accrued after 1997 would violate Dey's right to due process.

A. The Government's Knowledge of Dey's Prices Defeats the Government's FCA Claims as of 1997 for Dey's Albuterol Sulfate and Cromolyn, and as of 1999 for All of Dey's Drugs

In assessing whether the Government's knowledge precludes an FCA claim, the relevant inquiry is the depth of the Government's knowledge, not the circumstances in which the Government gained its knowledge. *Orenduff*, 548 F.3d at 954. Just as in *Orenduff*, by those dates the Government was aware of the same "universe of facts" as Dey regarding the pricing for the Subject Drugs, largely through pricing disclosures that Dey made publicly or directly to the Government. The Government augmented its knowledge regarding the pricing for Dey's inhalation drugs through its own OIG investigations, beginning with a 1996 published report on albuterol. Indeed, it conducted its own investigations for reports published in 1996, 1997, 1998, and 2001. It requested Ven-A-Care to supply it with pricing information regarding the Subject Drugs, and Dey provided contract prices in response to a subpoena served by the OIG. Finally,

beginning in 1999, Dey wrote letters to state Medicaid administrators and DMERCs that stated what its published AWPs and WACs were.

1. Dey's WACs**.**

Dey has reported a WAC to pricing compendia such as First DataBank, Redbook, and Medispan for each of the Subject Drugs since launch. (SOF ¶ 76.) Dey's WACs are the prices that Dey invoices wholesalers that purchase its drugs. (SOF ¶ 73.) A significant number of wholesaler customers paid at or above WAC. (SOF ¶ 84.)

Over time, Dey decreased the WACs for the Subject Drugs as competition in the market place forced Dey to lower its prices. (SOF ¶ 74.) Dey's WAC is a meaningful number with economic implications for Dey because it is the basis for calculating chargebacks and discounts.[7] (Stiroh Decl. ¶¶ 6, 9.) Consequently, the downward adjustments to the published WACs for Dey's drugs reflect downward adjustments in prices charged by Dey for its products.[8] (SOF ¶ 74.)

Moreover, since Dey's WACs reflect prices that are actually charged for Dey's drugs, much of the so-called "spread" that the Government complains of is actually reflected in the difference between published AWPs and published declining WACs for Dey's drugs. (*See* Stiroh Decl., Figures A-K.) Indeed, by January 1, 1999, Dey was reporting AWPs and WACs that resulted in spreads of at least approximately 100% for all of the Subject Drugs. (*Id*.)

Review of these prices plainly reveals to anyone at all familiar with Medicaid or Medicare reimbursement that so-called "megaspreads" existed between published prices and

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[7] After excluding indirect sales to providers for which wholesalers simply act as intermediaries but taking into account the discounts and other price reductions wholesalers receive, the majority of Dey's sales to wholesalers are at prices within five percent of the published WACs for Dey's drugs. (Stiroh Decl., Ex. 6.)

[8] The only exception was for three NDCs relating to albuterol unit dose where Dey raised its WAC to FDB (but not Redbook or Medispan) after being told by the head of Florida Medicaid that Dey needed to do that in order to compete in the Florida market. Dey reported a lowered WAC approximately six months later, although FDB failed to make the change for another year. (*See* Ex. 296.)

acquisition costs. By making these prices publicly available, Dey was certainly not concealing, but was rather revealing, that its prices were declining as a result of generic price competition.

2. Dey's AMPs**.**

The Rebate Agreement between CMS and the states defines AMP as "the average unit price **paid** by wholesalers" to Dey "for drugs distributed to the retail pharmacy class of trade" and "include case discounts and all other price reductions … which reduce the actual price paid." (SOF ¶ 89.) CMS uses the AMPs it receives from Dey to calculate the Unit Rebate Amount, or URA, an NDC-specific, per-unit amount. (SOF ¶ 94.) CMS forwards the URAs on to state Medicaid programs, who multiply the URAs by the number of units dispensed to determine the final rebate amount Dey will pay. (SOF ¶ 95.) Former administrators of CMS admitted that CMS employees could have compared Dey's AMPs to published prices for the Dey Subject Drugs to determine the difference between those prices. (SOF ¶ 92.) For the majority of the Subject Drugs, the URA is simply 11% of the AMP (10% prior to January 1, 1994). *See* 42 U.S.C. 1396r-8(c)(3). The AMPs for Dey's products follow the same downward trend as the published WACs during the relevant time period. (Stiroh Decl., Figures A-K.) Like the WACs, the decreasing AMPs reflect the lower prices Dey charged for the Subject Drugs as other generic versions entered the market. Unlike the WACs, the AMPs reflect the various discounts and price reductions Dey offers to its customers, as required by the Rebate Agreement and federal law.

3. FSS Data**.**

The Government, through the Department of Veterans Affairs and the Department of Defense, negotiates FSS prices for federal purchases of pharmaceuticals. (SOF ¶ 110.) The FSS prices are not confidential and recent prices are reported by the US Department of Veterans Affairs on their web site. (SOF ¶ 114.) FSS prices are on average 50 to 58 percent lower than AWP. (Ex. 43 at 9-10.) These prices for the Dey Subject Drugs were available and known to

the Government throughout the relevant time period, and are specifically referenced by the OIG in its reports. (SOP ¶ 129.)

4. Government Reports for the Dey Subject Drugs**.**

Beginning at least as early as 1995, the OIG has repeatedly conducted its own studies comparing Medicare and Medicaid reimbursements to prices actually paid in the market place for the Dey Subject Drugs, particularly albuterol and ipratropium. The Government obtained pharmacy invoices, wholesaler catalog prices, and FSS prices for the Dey Subject Drugs and analyzed them as a part of the publication of over ten OIG reports which directly address the drugs at issue here. (SOF ¶¶ 117-135.)

a. Albuterol Sulfate

The Government has produced invoices for Dey's albuterol dated from as early as 1994, and the OIG has published ten (10) reports *specifically* studying the acquisition cost of albuterol beginning in February, 1996, and subsequently in June, 1996 (two reports), December, 1997, August, 1998, November, 1998, June, 2000, January, 2001, March, 2002, and January, 2004. (SOF ¶ 117.) As the working files from these early reports demonstrate, the acquisition cost of Dey's albuterol was specifically examined by the OIG. For instance, a memo dated November 8, 1995 from "Karen" to "Rob," "Bob," and "Amy," discusses invoices the Government received from Medicare suppliers for Dey's albuterol sulfate 0.083%. (SOF ¶ 124.) The memo notes that the lowest price suppliers pay to Dey for albuterol sulfate is $0.1167 per milliliter, and the highest price paid by suppliers for Dey's albuterol sulfate was $0.1667 per milliliter. (SOF ¶ 125.)

The almost yearly publication of albuterol reports further documented the actual ingredient cost for albuterol sulfate. For example, in "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996), the OIG concluded that members of pharmaceutical

buying groups could purchase albuterol sulfate for between 56 and 70 percent lower than the $0.43 per milliliter paid by Medicare at the time. (SOF ¶ 118.) In the Government's parlance, this results in a spread of as much as 230%. In "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996), the OIG concluded that Medicare suppliers could acquire albuterol sulfate as low as $0.12 per milliliter, while the price paid by Medicare was $0.43 per milliliter. (SOF ¶ 119.) This difference between these two figures that were published by the OIG results in spreads of as much as 258%.

The OIG made similar findings in later reports as follows: in December, 1997, it reported that the actual AWP for albuterol sulfate in 1995 was $0.15, $0.17 lower than the $0.42 average Medicare reimbursement amount for that time (SOF ¶ 120); in August, 1998 it reported that Medicare will pay between 56 and 550 percent more for albuterol than FSS prices available to the VA and up to 333 percent more than some pharmacies pay to acquire albuterol (SOF ¶ 121); and in November, 1998, it reported that the median price for the Department of Veterans Affairs (the "VA") to purchase albuterol sulfate unit dose was $0.12, while Medicare's median allowable price was $0.47, resulting in a 292 percent spread (SOF ¶ 122.)

b. Ipratropium Bromide

The Government also specifically studied the actual acquisition cost of another of the Subject Drugs, ipratropium bromide, beginning at least as early as 1998, and the working files from the OIG indicate that the OIG also reviewed various prices for Dey's ipratropium which Dey introduced in January, 1997. (SOF ¶ 127-131.) In "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293, the OIG found that the VA's median price for ipratropium bromide was $1.31, while Medicare's median allowable price was $3.34, resulting in a 155% spread. (Ex. 51 at App. B-1.) A document produced from the OIG's working files, dated May 21, 1998, lists Federal Supply Schedule prices for several drugs,

including Dey's albuterol sulfate and ipratropium bromide products. (Ex. 58.) That document lists a Federal Supply Schedule price for Dey's ipratropium bromide 0.02% inhalation solution (NDC 49502-0685-60) of $40 per unit. (*Id.*) Another document bearing the same Bates prefix and date January 1998 appears to be a print out of various AWP prices from Red Book. (Ex. 59.) The AWP listed for the corresponding ipratropium bromide product on this document is $105.60. In 2001 and again in 2002, the OIG continued to find and to report that there were large spreads for ipratropium.[9]

c. Cromolyn Sodium

The OIG working files also contain pricing information for Dey's cromolyn sodium. For example, a February, 1996 fax from Robert Zone to Robert Vito at the OIG contained a contract showing the price of Dey's cromolyn to be $60 per package. (Ex. 62.) Mary Riordan, an attorney from the Office of Counsel to the Inspector General, produced copies of a Pharmaceutical Buyers, Inc. catalog dates November 28, 1995, which listed contract prices for Dey's cromolyn at $28.00. (SOF ¶ 133.) Ms. Riordan also produced a contract between Dey and Gerimed with an effective date of August 1, 2006, listing contract prices for cromolyn at $25.00 and $49.00. (SOF ¶ 134.)

[9] *See* HHS-OIG, "Medicare Reimbursement of Prescription Drugs" OEI-03-00-00310 (January 2001), which found that a median VA price of $0.84 per milligram, whereas the median Medicare allowable amount was $3.34, creating a spread of 297 percent. The report also found that the catalog price for ipratropium was $1.53, creating a spread of 118 percent. *See also* HHS-OIG "Excessive Medicare Reimbursement for Ipratropium Bromide" OEI-03-01-00411 (March 2002); finding the median Medicare allowable cost for ipratropium bromide was $3.34, while the median VA price for ipratropium bromide was $0.66, resulting in a "spread" of 406 percent. The report also contained a chart, tracking the Medicare allowable amount against the VA prices between 1998 and 2001. Much like relationship between Dey's AWPs and WACs, the Medicare allowable amount, (which was the median AWP for all the generic sources of ipratropium bromide less five percent during that period) remains constant at $3.34, while the VA median price steadily decreases, starting at $1.29 in 1998 and dropping to $0.66 in 2001. The report also found that the median price for ipratropium appearing in wholesale catalogs was $0.82 per milligram, creating a spread of 307 percent between the catalog price and the Medicare allowable amount.

This Court has previously held that the reports that resulted from these studies played a large role in putting private third-party payors such as Blue Cross/Blue Shield on notice that AWP did not represent actual acquisition costs as of 1997. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 78 (D. Mass. 2007). If the reports were sufficient to apprise third-parties that published prices did not reflect providers' acquisition costs, they were certainly sufficient to inform the Government.

5. Ven-A-Care Filing and the Government's Investigation

In addition to the information available through Dey's reported prices, its AMP, FSS prices, and the OIG investigations, the Government also requested and received pricing information regarding the Dey Subject Drugs from Ven-A-Care and through the OIG's own subpoenas served on Dey. Additionally, Ven-A-Care served its first *qui tam* complaint against Dey, which included claims for Dey's albuterol sulfate unit dose and cromolyn sodium, in August 1997. (SOF ¶ 142.) The Government was aware of all of the allegations concerning albuterol and cromolyn prior to this filing. (SOF ¶ 142.) For this reason, the Government's claims for damages should stop for these drugs at the time of filing. Ven-A-Care amended its *qui tam* in December of 1999 to include allegations concerning Dey's ipratropium bromide. (SOF ¶ 142.) The OIG issued a first subpoena to Dey on or about October 31, 1997 and a second subpoena on or about July 27, 2000. (SOF ¶ 144.) Over an eight year period from October 1997 to September 2005, Dey produced or made available for inspection approximately 2.3 million pages of documents on at least eight separate occasions to the OIG (most of which were also produced to Ven-A-Care in connection with the Texas and/or Florida pricing litigations). (SOF ¶ 145.) As of December, 1997, Dey had produced 2697 pages of documents, which included various contract awards listing contract prices and other pricing information for

cromolyn and albuterol. (SOF ¶ 146.) In addition, the OIG requested additional pricing information from Ven-A-Care which Ven-A-Care later supplied.

In the late 1990's, Ven-A-Care and the DOJ discussed their investigation at the annual conference of the National Association of Medicaid Fraud Control Units ("NAMFCU"), and nearly every state attended. (SOF ¶ 141.) They also made several presentations to CMS during this time. (SOF ¶ 141.)

6. Price Notification Letters

By 1999, Dey began sending the letters describing what its published AWPs and WACs represented in letters sent to state Medicaid administrators, and at least once, DMERCs. (SOF ¶¶ 148, 149.) These letters clearly stated that Dey's AWP was not a price actually charged or paid in the market place and that Dey's WAC was its undiscounted price to wholesalers. (SOF ¶¶ 152, 153.) Dey has sent numerous letters containing this language to state Medicaid administrators since 1999, containing the same or similar language. (SOF ¶ 148.) There is no evidence in the record that any state Medicaid administrator ever contacted Dey to voice concern regarding these statements. (SOF ¶¶ 155, 158.) Many state Medicaid officials who recalled receiving such letters from Dey testified that they never contacted anyone from Dey about the statements made in the letters. (SOF ¶ 156.)

There is no issue of fact that Dey's practices with regards to setting WACs and AWPs were consistent with what was described in these letters. Thus these prices could not reasonably be considered false; nor could Dey have knowingly caused the submission of false or fraudulent reimbursement claims by continuing to set its prices in the manner in which it told the Government it did. These letters, along with the other pricing information the Government had received since the launch of Dey's albuterol, ipratropium, and cromolyn, provides the "perfect storm" of information for these Subject Drugs.

7. Additional Information After 1999

This Court has already stated that "[b]y 2001, there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General ("OIG"). In addition, the press began to report on the rampant abuse of the AWP system." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 41 (D. Mass. 2007). For Dey's Subject Drugs, at least by 1999, there existed such a perfect storm of information relating to Dey. However, even after Dey began sending letters regarding its AWPs and WACs in 1999, the Government continued to obtain pricing and other information regarding the Dey Subject Drugs. For example, the OIG obtained invoices for Dey's albuterol in connection with "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the West Virginia Health and Human Resources" (A-06-01-00007) (SOF ¶ 135.) Also, the OIG published three additional reports studying albuterol in 2000, 2002, 2004 and reports on ipratropium in 2001 and 2002. (SOF ¶¶ 117, 131.) In addition, albuterol pricing was studied in the Medicare context. Despite Medicare's inherent reasonableness authority to implement lower prices, lower prices for albuterol sulfate were not implemented, and were in fact prohibited by Congressional action in 1999. *See supra* at page 11-12.

Also, both Medicare and Medicaid rejected lower prices for Dey's albuterol sulfate and cromolyn in 2000. On September 8, 2000, CMS issued a program memoranda to its Medicare Carriers which announced alternative AWPs "from wholesalers' catalogs that list the prices at which the wholesaler sells the respective products." (SOF ¶ 195.) According to the memo "The DOJ has indicated that these are more accurate wholesale prices for these drugs. Furthermore, the DOJ has indicated that because purchasers often receive further discounts below the advertised wholesale catalog price, either from a wholesaler or from the drug manufacturer

directly, actual acquisition costs may be lower." (Ex. 181.) The memo accompanying the revised AWPs included the specific example of albuterol: "For example, the DOJ data from wholesale catalogs indicates an average wholesale price of $22 for one albuterol sulfate NDC which is substantially less than the $73 average wholesale price in the Redbook and compares to $15 from a GPO. These data are generally consistent with findings from OIG reports." (*Id.*) CMS issued lower revised AWPs for Dey's current albuterol and cromolyn NDCs. (SOF ¶ 198.)

On November 17, 2000, a little over two months after they were first implemented, Medicare suspended, the DOJ AWPs, stating "While we continue to believe that the AWPs reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source." (SOF ¶ 202.) The revised AWPs for Dey's albuterol and cromolyn were also circulated to state Medicaid agencies. (SOF ¶ 261.) The DOJ AWPs were rejected by many states in whole or in part. (SOF ¶ 262.)[10]

B. Due Process Bars the Government's Claims After 1997

In addition, the principles of due process preclude the Government from seeking damages against Dey after 1997, as the Government has exploited the nine-year seal period in this action "to gain an unfair tactical advantage over [Dey]" or, at the very least, put off proceeding with this action "in reckless disregard of [the] probable prejudicial impact upon the defendant's ability to defend against the charges." *See United States v. Eight Thousand Eight Hundred and Fifty Dollars in U.S. Currency*, 461 U.S. 555, 563 (1984) (articulating the standard under which the Government's delay in prosecuting an action can violate a defendant's right to

[10] Throughout CMS's experiment with the revised AWPs, the WACs that Dey voluntarily reported to the pricing compendia for the four albuterol and two cromolyn NDCs were in fact lower than the revised AWPs for those NDCs as calculated by the DOJ and NAMFCU. *Compare* Ex. 181 *to* Stiroh Decl., Figures E, F, G, I, J &K.

due process). This Court has previously recognized the due process concerns caused by such delays. *See Dey*, 498 F. Supp. 2d 389, 399 (D. Mass. 2007). Now that discovery is complete, the record is clear that the Government's nine year delay in intervening has violated Dey's right to due process through the loss of key evidence, [11] the tactical advantage the Government has gained through nine years of one-sided discovery, and the running up of damages in violation of the Supreme Court's holding in *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 187 (1997).

The Government seeks to recover for claims that accrued *after* Ven-A-Care filed its first *qui tam* complaint against Dey until 2004 for Medicare and to date for Medicaid. *See* Amended Complt. at ¶ 50. Allowing the Government to recover on claims that accrued after Ven-A-Care filed its original complaint against Dey "would permit plaintiffs who know of the defendant's pattern of activity simply to wait, 'sleeping on their rights,' as the pattern continues and treble damages accumulate, perhaps bringing suit only long after the 'memories of witnesses have faded or evidence is lost.'" *Klehr*, 521 U.S. at 187 (internal citations omitted). Of course, the Government was not prejudiced by this delay, as it used the nine year seal period to engage in one sided discovery – including subpoenaing documents, interviewing witnesses, coordinating efforts with state attorneys general, retaining experts, and developing damages models. (SOF ¶ 143.) Even if the Government did not intend by its conduct to gain an unfair tactical advantage over Dey in this lawsuit, the Government's reckless disregard to the prejudice its conduct caused Dey is a clear violation of Dey's right of due process. Accordingly, the Court should bar all claims for damages after 1997.

[11] *See* Dey's Motion for Finding of Spoliation and Sanctions (Dkt. No. 6109) and supporting papers, which deal with the loss of critical evidence caused by the Government's nine year delay in unsealing this action.

III. DEY IS ENTITLED TO SUMMARY JUDGMENT ON NUMEROUS OF THE GOVERNMENT'S CLAIMS FOR DAMAGES

A. Dey Is Entitled to Summary Judgment for Those Claims the Government Cannot Prove Were Paid on the Basis of Dey's AWPs and WACs

To survive summary judgment, the Government must provide proof that claims for payment were actually submitted. *See United States ex rel. Aflatooni v. Kitsap Physicians Services*, 314 F.3d 995, 1002-03 (9th Cir. 2002) (affirming dismissal of FCA action on summary judgment where, despite evidence that defendants engaged in a fraudulent scheme, there was no evidence of a single, actual claim for payment submitted). It is not sufficient for plaintiff to show that the submission of false claims was statistically likely; the plaintiff must demonstrate that claims were actually submitted. *See United States ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853, 856-58 (7th Cir. 2006) (dismissing FCA claims where the relator had demonstrated that it was statistically likely that claims had been submitted to the Medicaid program, but had failed to demonstrate the actual existence of any claims).

Moreover, to recover for damages, the Government must prove causation – specifically that the defendant caused the Government to pay claims "because of" the alleged false statements. *See* 31 U.S.C. § 3729(a); *United States v. Hibbs*, 568 F.2d 347, 351 (3d Cir. 1977); *United States ex rel. Fago v. M & T Mortgage Corp.*, 518 F. Supp. 2d 108, 120 (D. D.C. 2007). Courts have specifically noted the statute's restrictive language "because of" and have adopted the direct and proximate causation standard when determining actual damages in FCA cases.

This Court has previously dismissed claims in which the plaintiff has not alleged or established a link between the alleged wrongdoing and the payment basis. In *In re Pharm. Indus. Average Wholesale Price Litig. (California ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc.)*, this Court dismissed the First Amended Complaint as it relates to the drugs reimbursed on a Maximum Allowable Ingredient Cost (MAIC) methodology. *See* 478 F. Supp.

2d 164, 180 (D. Mass. 2007). Here, where the Government has alleged that Dey reported inflated AWPs and WACs, this Court should, at the minimum, grant Dey summary judgment for those claims that have not been shown to have been caused by Dey's published prices for the subject drugs. As discussed in more detail below, Dey is entitled to summary judgment on these claims because the record contains no claims data for a particular state or time period, because the claims data clearly demonstrates that the payments were made on a basis other than Dey's published prices, or, in the case of Medicare, where the Government can point to no evidence in the record that particular claims were paid based on Dey's published prices. Dey in no way concedes that the claims data used by the Government is otherwise adequate. Dey is simply focusing on these glaring deficiencies for purposes of this motion.

States have a variety of definitions of "EAC," including basing EAC on AWP minus a percentage decrease or WAC plus a percentage increase. (SOF ¶¶ 218, 274, 276.) EAC is only one element in typical the lower-of methodology, which also considers the usual and customary charge, FULs, and state MACs. (SOF ¶¶ 273, 274, 276.) As a result of these formulae, Medicaid reimbursement is only "set based on the inflated AWPs and WACs", as alleged by the Government, when a particular claim is paid based on an EAC that is in turn set on AWP or WAC. (Ex. 13 ¶ 51.) The Amended Complaint does not contain any specific allegations relating to claims paid on the FUL, MAC, the usual and customary charge, or any payment bases other than AWP and WAC. Therefore, for the Government to recover for FCA damages, the Government must show that the alleged AWP or WAC misrepresentations that Defendant made were the direct and proximate cause of the Government's losses.

In the case of Medicare, the Government alleges that reimbursement is based on a median AWP, and not on the exact AWP reported by Dey. (Ex. 13 ¶¶ 45-47.) The median is determined

by the DMERCs and can vary depending on the NDCs chosen by the DMERCs for inclusion in the array. (SOF ¶¶ 171, 172, 185-187.) Therefore, the Government cannot show causation where there is no evidence of what was in the array or where Dey's published prices had no material effect on the median.

1. This Court Should Grant Dey Summary Judgment on the Government's Medicaid Allegations for Those States and Time Periods With Missing State Level Claims Data Necessary to Determine Payment Bases

Because the Government has not provided sufficient evidence in the form of comprehensive state-level claims data, Dey should be granted summary judgment on the Government's Medicaid allegations for those missing states and time periods. In addition, this Court should grant Dey summary judgment on the issue of damages for those claims missing state-specific claims data because without this claims data, the Government cannot prove that the alleged AWP or WAC misrepresentations made by Dey resulted in any "false claim" being made, or that, if made, were the direct and proximate cause of the Government's losses.

State by state claims data is necessary to prove the payment bases for particular claims; *i.e.*, whether a particular claim submitted by a provider to Medicaid was paid on the basis of EAC, MAC, FUL, Usual or Customary, or some other measure. This individual-level claims data, as utilized by the Government's damage expert, Dr. Mark Duggan for the 14 states he examines, is the only way to accurately determine what was paid for Dey's drugs, and why.[12] Summary-level claims data, such as the SDUD and MAX/SMRF data utilized by Dr. Duggan, does not sufficiently identify the payment basis for each claim, and therefore cannot be used to prove that Dey's AWP or WAC caused the Government damages. (Ex. 13 ¶¶ 45-47.) One

[12] Even for the 14 states for which Dr. Duggan examines state claims data, he still must extrapolate using SDUD and MAX/SMRF data for various periods of time for those states.

major problem with using SDUD and MAX/SMRF summary data or any projections based on a state's stated reimbursement rate is that, in many cases, there are discrepancies between a state's reimbursement policies and that state's actual reimbursement practices. (Bradford. Decl., Figure 5.) Such discrepancies cannot be determined from the CMS data, but only from the state claims data.[13]

SDUD and SMRF/MAX data are also inadequate because they do not contain all of the information needed to determine how much was paid for each claim. First, SDUD is aggregate data and therefore does not provide sufficiently detailed circumstantial evidence to establish a false claim as it is aggregate data. (SOF ¶ 287.) This summary, aggregate data lists the state, the NDC, the name of the drug, the total units reimbursed for that quarter, the total number of prescriptions for the quarter, the total amount reimbursed for that NDC for the quarter, and quarter covered. (*Id*.) For example, the data may list 100 prescriptions for a particular Dey NDC for a particular quarter, and a total amount paid of $500.00 for that quarter. From this data, there is no way to determine if some of those prescriptions were returns, how much was paid on a per prescription basis, who submitted or received the payment, or a variety of other factors necessary to determining whether an actual "false claim" was submitted. Dr. Duggan himself acknowledges inadequacies with the data.[14] It is impossible to determine how much was paid on a claim by claim basis using SDUD, so Dr. Duggan instead must extrapolate using data gathered

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[13] For example, Hawaii used reimbursement formulas that conflicts with its state plans. After 2001, in instances where there was a FUL for a drug that was higher than the state MAC, it was Hawaii's practice to reimburse at the higher FUL. (SOF ¶ 250.) Indeed, this Court has already recognized that Massachusetts did not follow its State Plan, but instead used AWP less a percentage as a "proxy" for WAC in instances where a WAC was not reported. Massachusetts failed to include this policy in its State Plan Amendment or otherwise inform Defendants of this policy. *See Mylan Labs*, 608 F. Supp. 2d at 147-48.

[14] "For many of the remaining 30 states with substantial differences between the two data sets, the aggregate SDUD data appears to be incomplete." (Ex. 270 at 29.)

from the state-specific individual claims data. (Ex. 270 at 38.) Furthermore, the SDUD does not show whether Dey's AWP or WAC were actually used to pay claims. (Bradford Decl. ¶ 26.)

Second, MAX/SMRF data is insufficient because it also does not provide sufficient detail to serve as a "false claim" under the FCA. Though MAX/SMRF data has some claims-level data, it is not available for all states prior to 1999, and does not include quantity for any state prior to 1996. (SOF ¶ 288.) Duggan identifies the shortfalls of the MAX/SMRF data, and once again uses a formula that relies on the actual claims data for other time periods in estimating damages using SMRF/MAX data.[15] (Ex. 270 at 51.) MAX/SMRF also does not include dispensing fee and co-payments, which reduces the precision of attempts to calculate the reimbursement basis. (Bradford Decl. ¶ 27.) MAX/SMRF data is also rounded, which further reduces the precision of payment basis analysis. (*Id*.) Due to these deficiencies, it is not possible to determine how claims were actually paid – a calculation that can be performed using state claims data.

2. For Those States with Medicaid Claims Data Used by the Government, Dey Is Entitled to Summary Judgment on Claims Not Based on Dey's Published Prices.

For those states for which there exists claims data, the Government cannot prove causation for claims paid on bases other than Dey's AWP and WAC. Therefore, this Court should grant Dey summary judgment on those claims paid on the basis of: (1) unidentified payment bases, (2) state MACs; (3) the providers' usual and customary charge; and (4) the FUL.

[15] For the period from 1996-1998, Duggan states that the MAX/SMRF is only available for 28 states (Ex. 270 at 30.) He also states that "Relatively few of the states have SMRF data for all four years" from 1992 to 1995 (*Id*.) "Large differences in total Medicaid spending between the two data sets are more common from 1992 to 1995 . . . . though this is primarily because many states do not have SMRF claims data for all four of these years." *Id*.

As set forth elsewhere, because Dr. Duggan only looks at 14 states' claims data, Dey should be granted summary judgment for the remaining states' claims.[16]

a. This Court Should Grant Dey Summary Judgment On Medicaid Claims Paid Based on State MACs

In the California action, this Court dismissed the First Amended Complaint as it related to the drugs reimbursed on a MAIC methodology because the plaintiff failed to allege a link between defendants' published AWP or WACs and reimbursement payments for those drugs. *Abbott Laboratories*, 478 F.Supp.2d at 180. Similarly here, the Court should grant Dey summary judgment on those claims that can be shown to have been paid on the basis of state MACs that that the Government cannot otherwise show were derived from Dey's AWPs or WACs. *See* SOF ¶ 235-237.

Many states set their MAC for the Subject Drugs on prices other than published AWPs and WACs. For example, Minnesota's MACs are based on actual acquisition costs that were provided by a group of pharmacies. (SOF ¶ 232.) An analysis of the claims data demonstrates that 34.2% of the claims for the subject drugs in Minnesota were based on the MAC. (Bradford Decl., Figure 5.) Dey should be granted summary judgment for these 34.2% of claims. In Georgia, MACs are determined by pharmacy benefit managers who have their own proprietary methods for calculating the MACs, which they don't share with the State. (SOF ¶ 234.) 65.2% of the Georgia claims were paid based on MAC. (Bradford Decl., Figure 5.)

b. This Court Should Grant Dey Summary Judgment On Medicaid Claims Paid Based on Other Unidentifiable Bases

In many instances, even if there is state-specific claims data for a particular state, it is not possible to determine the basis of payment. This could result from a variety of factors, including

[16] Dey does not concede that the data from the 14 states upon which Dr. Duggan relied for his extrapolations is sufficient to establish damages for those 14 states either.

when a state does not follow its stated reimbursement methodology. The Government cannot demonstrate that Dey's published AWP or WACs caused these unidentifiable payments. Therefore, Dey cannot be held responsible for damages as a result of these payments. For each state for which state-specific claims data has been produced, a percentage of claims were paid on an amount other than that of AWP, WAC, FUL, MAC, and the billed charge, and the percentage of "other" claims ranges from 0.2% in Utah to 47.9% in Hawaii. (Bradford Decl., Figure 5.) For example, in New York, 27.2% of the claims for the subject drugs cannot be identified. (*Id*.) This is not a disputable proposition as Dr. Duggan, in those cases in which he examines state-level claims data, drops those claims "for which [he] is unable to replicate the amount paid." (Ex. 270 at 33.)

c. This Court Should Grant Dey Summary Judgment On Medicaid and Medicare Claims Paid Based on The Provider's Usual and Customary Charge or the Billed Amount

Pharmacy providers must submit their usual and customary charges to the states as a part of a claim for Medicaid. Each state has its own definition for "usual and customary charge". For example, Alabama Medicaid's provider manual defines "usual and customary charges" as an "amount which a provider usually and most frequently charges patients for a specific service in normal medical circumstances", and the Virginia Department of Medical Assistance Services' provider manual, appendix A, defines "customary charge" as "[t]he amount providers usually bill patients for furnishing particular services or supplies." (SOF ¶¶ 228, 229.) What all definitions have in common is the fact that the usual and customary charge is a price that is set by the provider, and is not set by Dey. (SOF ¶ 251.) Furthermore, the pharmacy providers must certify that the usual and customary charges that they submit are accurate. (SOF ¶ 255.) The Government has not contended that the usual and customary charge submitted by the providers are in any way fraudulent. (SOF ¶ 256.) Because claims paid on the basis of usual and

customary are paid on a price that is set by providers, is certified by providers, and because the Government has presented no evidence that providers consider Dey's AWP and WAC in setting their usual and customary charge, the Government cannot prove causation for those claims. An analysis of the claims data for those states for which it is available demonstrates that all states with claims data paid some claims based on the usual and customary billed charges, ranging from 0.9% in California to 34.8% in Alaska. (Bradford Decl., Figure 5.)

d. This Court Should Grant Dey Summary Judgment On Medicaid Claims Paid Based on the FUL

Dey should be granted summary judgment on all claims paid on the FUL. Dey is aware that this Court currently has summary judgment motions on the issue of FUL pending in *City of New York, et al. v. Abbott Laboratories, et al.*, Civil Action No. 01-12257-PBS. The issue of causation between the reported AWP and WAC and the FUL is fully briefed in that case, and Dey's position is set forth by the joint defendants in that case.[17]

B. This Court Should Enter Judgment Dismissing All Medicaid Claims in Arizona, Ohio, and Texas

The Government has stated that it is not seeking damages for Ohio, and Dr. Duggan does not include Arizona, Ohio, and Texas in his calculations. (Ex. 270, page 28, fn17.) Because the the Government has not set forth any damages or evidence for these three states, this Court should grant summary judgment in favor of Dey for Arizona, Ohio, and Texas.

C. Dey Is Entitled to Summary Judgment on Certain of the Government's Medicare Claims

This Court should grant summary judgment for all Medicare claims for which the Government cannot prove that Dey has caused the Government to pay claims "because of" the alleged false statements. *See* 31 U.S.C. § 3729(a). Unlike Medicaid, Medicare reimburses for

[17] Dey hereby incorporates the Joint Defendants' Motion for Summary Judgment on the FUL Claims in the New York Counties Actions. (SOF 249.)

covered prescription drugs by using a 5-digit alphanumeric code, the Healthcare Common Procedural Coding System ("HCPCS" or "HCPCS Code"). Each DMERC compiled a pricing array for each HCPCS on a quarterly basis and calculated the median generic or lowest brand price to determine the allowed reimbursement level. (SOF at ¶170.)

1. Dey Is Entitled to Summary Judgment on the Issue of Damages for Those Payments Made by DMERCs Where Dey's Price is Not Included in the Array and for Periods Without Documented Arrays.

In order to prove causation in the Medicare context, the Government must demonstrate that Dey's AWP was included in and could have affected the median calculation. As stated by Dr. Duggan, "to the extent that the same AWP of Dey products influences the median in these calculations, Medicare spending is also affected." (Ex. 270 at 11.) As a fundamental principle, Dey's AWP could not have affected the median were it not included in a particular array. Dr. Duggan has attributed differences to Dey for some of the Subject Drugs even in quarters when Dey NDCs were not included in the DMERC arrays. (Bradford Decl. ¶ 35.) In other words, the Government has claimed damages when the DMERC was not relying on published prices for Dey drugs to determine the allowable. Because there is no way to prove causation when Dey was not listed in a given array, this Court should grant summary judgment in favor of Dey for all arrays where Dey is not listed.

Furthermore, the Government has attempted to circumvent causation by extrapolating arrays for particular carriers and time periods that were missing arrays and by including Dey in these arrays. (Bradford Decl. ¶ 34.) This approach cannot be used as evidence in support of causation. Although payment policies for Medicare Part B are set at the Federal level, regional DMERCs had considerable latitude in implementing these policies. Because various DMERCs used their discretion to compile data for the arrays, there are differences in the prices listed in the arrays across DMERCs. Cheryl Eiler of Administar Federal testified: "We would try to use the

products that best suited the narrative description of the HCPCS code that we were given in order to calculate the fee. And sometimes other regions may have used a different product than I would have used, and that would be the discrepancy, or used a different package." (SOF at ¶ 172.) A review of the arrays relied on by Dr. Duggan reveals that there are differences across DMERCs and time periods relating to which products appear in which arrays. Just because a product appears in a pricing publication does not ensure that it would appear in a DMERC's corresponding array, given the discretion allowed to DMERCs and other factors, including human error. Therefore, the Government cannot rely upon extrapolated arrays for which there is not a corresponding array from a DMERC. Dr. Duggan has relied upon ad hoc extrapolations that he never discloses in his report or his work papers to produce unrealistic arrays and calculate differences. Without an actual array that was used by a DMERC for a particular quarter to determine the allowed payment amount, the Government cannot prove causation because there is no way to determine whether Dey's AWP was (1) included in the array; and (2) could have affected the array median.

2. Dey Is Entitled to Summary Judgment on the Issue of Damages for Claims Paid for Dey's Cromolyn Sodium Under Medicare.

The Government has alleged no damages for Dey's Cromolyn NDCs under the Medicare program. They have not analyzed the cromolyn arrays nor calculated any difference for the cromolyn drugs under Medicare. As a result, this Court should grant Dey summary judgment on the allegations regarding reimbursement for cromolyn under the Medicare program.

3. This Court Should Grant Summary Judgment Dismissing Any Damages which Incorporate or Rely on Roxane's Conduct.

Roxane is not a party to this action, nor is there any allegation in the Amended Complaint that Dey colluded or conspired with Roxane. In fact Roxane's name does not even appear in the Amended Complaint. *See* Ex. 13. Accordingly, there is no legal theory on which Dey could be

liable for damages that were caused by Roxane, yet the Government's "differences" expert has calculations for just that. The fact that Roxane has also been sued by the Government does not justify the collective allocation of damages. The Government alleges that Dey marketed the spread to compete for market share, not to collude with Dey's primary competitor for generic ipratropium. Dr. Duggan's Dey/Roxane scenarios are unsupported by any rationale and directly contradict the Government's theory of the case. This Court should preclude any recovery based on such joint scenarios. In his expert report, Dr. Duggan calculates damages based on changing Dey's AWP in the arrays for each of the Subject Drugs. For ipratropium, however, where Roxane is listed in the array, Dr. Duggan adds three additional scenarios where he changes both Dey and Roxane's AWP. He describes the process as follows: "[a]n additional issue is that the United States has also sued the firm Roxane for its impact on both Medicaid and Medicare spending." (Ex. 270 at 11.) The Government has not provided any justification for substituting both Roxane and Dey's prices in the arrays. When asked at his deposition about his rationale, Dr. Duggan testified:

> And then later on, as I can see from the next page of this exhibit you've handed me, the Roxane prices are also revised as discussed, and Dey and Roxane in contrast to Alpharma and the other two pharmacists, Total Care, and AllScripts are being sued by the United States. The other firms are not. (SOF ¶ 292)

This result is especially absurd since Mr. Duggan did not even look at the prices of any of the other array manufacturers, but rather he apparently assumed that their AWPs (which are all within Dey's range) reflected actual acquisition costs since the Government had not sued them.

IV. DEY IS ENTITLED TO SUMMARY JUDGMENT ON THE GOVERNMENT'S UNJUST ENRICHMENT CLAIM

The Government's third cause of action seeks equitable relief for purported unjust enrichment by Dey. (Ex. 13 ¶¶ 50, 52.)[18] Under the doctrine of unjust enrichment, a plaintiff seeks restitution of a benefit conferred on another whose retention of the benefit at plaintiff's expense would be unconscionable. *See Massachusetts v. Mylan Laboratories*, 357 F. Supp. 2d 314, 324 (D. Mass. 2005). In order to recover under a theory of unjust enrichment, the Government "must show (1) an enrichment, (2) an impoverishment, (3) a relation between the enrichment and the impoverishment, (4) the absence of justification and (5) the absence of a remedy provided by law." *Id*. (internal citations omitted).

The Government's unjust enrichment claim fails as a matter of law for two independent reasons. First, the availability of an adequate remedy at law bars the unjust enrichment claim. Second, there is simply no evidence that Dey's was enriched in anyway by the alleged scheme.

A. The Availability of an Adequate Remedy at Law Supports Dismissal of the Unjust Enrichment Claim at This Time

"Where plaintiff has an adequate remedy at law, equity will not consider a claim for unjust enrichment." *Taylor Woodrow Blitman Constr. Corp. v. Southfield Gardens Co.*, 534 F. Supp. 340, 347 (D. Mass. 1982) (granting summary judgment to defendant where plaintiff had an adequate remedy at law). Here, the Government's unjust enrichment claim is premised on alleged "violations of federal and state law" and is therefore premised on the same underlying wrong alleged for its FCA claims. *See* Ex. 13 ¶ 70. The Government seeks treble damages and civil penalties under the FCA. The remedies available under these claims are as clear and

[18] The Court has previously held that the statute of limitation bars any unjust enrichment claims prior to August 23, 2000. *United States ex rel. Ven- A-Care of the Fla. Keys, Inc. v. Dey, Inc.*, 498 F. Supp. 2d 389, 400 (D. Mass. 2007).

complete as that which equity can afford. *Mylan Labs.*, 357 F. Supp 2d at 324. In such circumstances, an unjust enrichment claim cannot lie. *See Taylor Woodrow*, 534 F. Supp. at 347.

B. Dey Has Not Been Enriched by the "Scheme" Alleged

The Government has not – and cannot – show that Dey has been enriched as a result of purported overpayment by the Medicare and Medicaid programs to the providers that dispensed Dey drugs. In fact the evidence reveals the opposite: (i) over time Dey's revenues and profits for its albuterol, cromolyn, and ipratropium declined as more generic competition caused price declines; and (ii) Dey's market share for these generic drugs did not increase. Indeed, the Government concedes, as it must, that it was the providers that allegedly "received millions of dollars in excessive reimbursement," not Dey. (Ex. 13 ¶ 61.)

The Government's allegation that Dey earned "profits" "because of illegal inducements Dey arranged to be paid to its customers," (Ex. 13 ¶ 69), is not supported by the evidence. There is no evidence in the record that Dey realized an increase in profits from any "spread" that existed for the Subject Drugs. Rather, the evidence shows that the prices Dey charged for the Subject Drugs went down over time. (Stiroh Decl., Figures A–K.) Dey made less per unit sold over time as the spread grew for all of its generic drugs. Excluding rising sales as Dey first entered the market for these drugs, when paradoxically the "spread" was smallest, the pattern of Dey's sales is clear: as the markets for them matured, competition and the market power of wholesalers caused frequent price reductions. (Stiroh Decl., Figures A-K; Bradford Decl. ¶¶ 5-10.) Finally, Dey stopped selling its albuterol inhaler and multidose albuterol in 2003, and stopped selling cromolyn in 2008. (Marrs Aff. ¶¶ 27, 29.)

Nor is there any evidence to support the Government's allegation that the alleged scheme increased Dey's market share. For instance, even though Dey was the first manufacturer to introduce a generic version of its albuterol unit dose in 1992, there currently are at least six other

companies that sell generic versions of albuterol. (SOF ¶ 19.) Currently, there are at seven other companies that offer generic versions of ipratropium. (SOF 39.) The Government's experts have made no analysis of whether any "spread" or alleged marketing of such led to a single sale, let alone increase in Dey's profits or market share. On this record, there is no claim for unjust enrichment.

V. THE GOVERNMENT'S CLAIMS PRIOR TO AUGUST 2000 ARE BARRED BY THE STATUTE OF LIMITATIONS

The Government's FCA claims are governed by a six-year statute of limitations. *See* 31 U.S.C. § 3731(b) ("A civil action under section 3730 may not be brought … more than 6 years after the date on which the violation of section 3729 is committed…".) Although the Government did not file its complaint in intervention in this action until August 24, 2006, the Government seeks FCA damages for claims arising as early as 1992, relying on the 1997 *qui tam* complaint filed by Ven-A-Care against Dey as a placeholder to which the Government's complaint in intervention relates back for purposes of Rule 15(c)(1) of the Federal Rules of Civil Procedure. *See Dey*, 498 F. Supp. 2d at 396-400. However, as this Court has held, the Government's ability to relate the claims in its 2006 complaint in intervention back to Ven-A-Care's 1997 *qui tam* complaint is contingent upon the existence of subject matter jurisdiction over Ven-A-Care's complaint: "If the Court did not have jurisdiction over Ven-A-Care's first pleading, the government's complaint-in-intervention cannot properly relate back." *Id.* at 399-400. Dey is filing a Rule 12(h)(3) motion to dismiss Ven-A-Care and its *qui tam* complaints for lack of subject matter jurisdiction because the "public disclosure/original source" rule contained in 31 U.S.C. § 3730(e)(4) deprives this Court of jurisdiction over Ven-A-Care's complaints, as Ven-A-Care based the claims against Dey on publicly disclosed information of which Ven-A-Care was not the original source. If the Court dismisses Ven-A-Care's *qui tam* complaints for

lack of subject matter jurisdiction, then the Court should also enter an order dismissing the Government's FCA claims for damages which accrued before August 24, 2000 as untimely.

CONCLUSION

Accordingly, Dey respectfully requests that the Court grant Dey's motion for partial summary and enter an order dismissing the Government's claims for albuterol sulfate and cromolyn sodium that accrued after August 1997, all of the Government's claims that accrued after January 1999, directing an entry of judgment finding no damages for the Government's claims as set forth, *supra*, in Section III, dismissing all of the Government's unjust enrichment claims, and, upon entry of an order dismissing Ven-A-Care and its *qui tam* complaints, all of the Government's claims that accrued before August 2000.

Dated: June 26, 2009

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on June 26, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid